WHAT IS CLAIMED IS:

1. A method of characterizing a multi-determinant metabolic phenotype for a class of N-(aryl substituted)-naphthalidimide compounds, wherein a plurality of phenotypic determinants are identified as corresponding to respective metabolic characteristics; said method comprising:

a) administering to an individual a probe substrate specific to metabolic pathway(s) for said class of N-(aryl substituted)-naphthalidimides compounds;

b) detecting metabolites of said metabolic pathway(s) in a biological sample from said individual in response to said probe substrate; and

c) characterizing respective phenotypic determinants of said multi-determinant metabolic phenotype based on detected metabolites.

2. The method of claim 1, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

3. The method of claim 2 which further comprises a step i) after step b):

i) quantifying a ratio of respective detected metabolites for each of said metabolic pathways in said biological sample.

4. The method of claim 3, wherein said ratio is selected from the group consisting of concentration ratio, molar ratio, chiral ratio, ratio of area under the curve and signal peak height ratio.

5. The method of claim 1, wherein said probe substrate is at least one probe substrate known to be metabolized by said metabolic pathway.

6. The method of claim 5, wherein said probe substrate is other than an inducer or inhibitor of said metabolic pathway.

7. The method of claim 1, wherein said step b) or step c) is effected using an affinity complexation agent specific to each of said metabolites.

8. The method of claim 7, wherein said affinity complexation agent is an antibody.

9. The method of claim 8, wherein said antibody is a monoclonal antibody.

10. The method of claim 8, wherein said antibody is a polyclonal antibody.

11. The method of claim 7, wherein said affinity complexation agent is a molecular imprinted polymer.

12. The method of claim 7, wherein said affinity complexation agent is an aptmer.

13. The method of claim 7, wherein said affinity complexation agent is a receptor.

14. The method of claim 7, wherein said affinity complexation agent is an anticalin.

15. The method of claim 7, further comprising a ligand binding assay.

16. The method of claim 15, wherein said ligand binding assay is selected from the group consisting of immunoassay, enzyme-linked immunosorbent assay (ELISA), microarray formatted immunoassay and microarray formatted ELISA.

17. The method of claim 15, wherein said ligand binding assay is a rapid immunoassay (Dipstick assay).

18. The method of claim 17, wherein said rapid immunoassay is based on Rapid Analyte Measurement Platform (RAMP) technology.

19. The method of claim 17, wherein said rapid immunoassay is based on light-emitting immunoassay technology.

20. The method of claim 15, wherein said ligand binding assay is performed with a biosensor.

21. The method of claim 20, wherein said biosensor is an immunosensor.

22. The method of claim 20 wherein wherein the means of detection of said biosensor is an electrochemical sensor.

23. The method of claim 20, wherein the means of detection of said biosensor is an optical sensor.

24. The method of claim 20, wherein the means of detection of said biosensor is a microgravimetric sensor.

25. The method of claim 24, wherein said microgravimetric sensor is a quartz crystal microbalance (QCM).

26. The method of claim 1, wherein step b) is effected by using a qualitative detection instrument.

27. The method according to claim 1, wherein each of said plurality of phenotypic determinants of said multi-determinant metabolic phenotype is an enzyme-specific determinant.

28. The method according to claim 27, wherein said multi-determinant metabolic phenotype is comprised of at

least one determinant indicative of an individual's metabolic capacity for at least one drug metabolizing enzyme.

29. The method of claim 28, wherein said at least one drug metabolizing enzyme is N-acetyltransferase-2 (NAT2).

30. The method of claim 29, further comprising CYP1A2.

31. The method of claim 30, further comprising at least one drug metabolizing enzyme selected from the group consisting of N-acetyltransferase-1 (NAT-1), CYP2D6, CYP2A6, CYP2E1, CYP3A4, CYP2C9 CYP2C19, UGTs, GSTs, and STs.

32. The method of claim 3, wherein step a) is effected by using a plurality of probe substrates and wherein each probe substrate is specific to at least one metabolic pathway of interest.

33. The method of claim 1, further comprising:

d) measuring at least one determinant for drug clearance known to affect the toxicity or efficacy of said class of N-(aryl substituted)-naphthalidimide compounds; wherein said at least one determinant is factored together with at least rate of probe substrate metabolism to determine a non-toxic and effective amount of said class of N-(aryl

substituted)-naphthalidimide compoundsto be administered to said individual.

34. The method of claim 33, wherein said at least one determinant for drug clearance is based on body surface area or hepatic enzyme levels of said individual.

35. The method of claim 1, further comprising:

d) measuring at least one determinant for drug susceptibility known to affect the toxicity or efficacy of said said class of N-(aryl substituted)-napthalidimide compounds; wherein said at least one determinant for drug susceptibility is factored together with at least rate of probe substrate metabolism to determine a non-toxic and effective amount of said class of N-(aryl substituted)-napthalidimide compoundsto be administered to said individual.

36. The method of claim 35, wherein said at least one determinant for drug susceptibility is based on white blood cell count (WBC) of said individual determined prior to step a).

37. The method of claim 36, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

38. The method of claim 34, further comprising:

e) measuring at least one determinant for drug susceptibility known to affect the toxicity or efficacy of said said class of N-(aryl substituted)-naphthalidimide compounds; wherein said at least one determinant for drug susceptibility is factored together with at least rate of probe substrate metabolism to determine a non-toxic and effective amount of said said class of N-(aryl substituted)-naphthalidimide compoundsto be administered to said individual.

39. The method of claim 38, wherein said at least one determinant for drug susceptibility is based on white blood cell count (WBC) of said individual determined prior to step a).

40. The method of claim 39, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

41. A method of using a multi-determinant metabolic phenotype to individualize a treatment regimen for a class of N-(aryl substituted)-naphthalidimide compounds for an individual, wherein the multi-determinant metabolic phenotype of said individual is determined; a safe and therapeutically effective dose of said said class of N-(aryl substituted)-naphthalidimide compoundstreatment is determined and/or selected based on said multi-determinant metabolic phenotype of said individual.

42. The method of claim 41, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

43. The method of claim 42, wherein said multi-determinant metabolic phenotype is determined according to the method comprising:

a) administering to an individual a probe substrate specific to metabolic pathway(s) for said class of N-(aryl substituted)-naphthalidimides compounds;

b) detecting metabolites of said metabolic pathway(s) in a biological sample from said individual in response to said probe substrate; and

c) characterizing respective phenotypic determinants of said multi-determinant metabolic phenotype based on detected metabolites.

44. A method of treating an individual having a condition treatable with a class of N-(aryl substituted)-naphthalidimide compounds, with a class of N-(aryl substituted)-naphthalidimide compounds, said method comprising:

a) determining a multi-determinant metabolic phenotype of said individual; and

b) administering a safe and therapeutically effective dose of said class of N-(aryl substituted)-naphthalidimide compoundsto said

individual, wherein said dose has been determined based on a metabolic profile of said individual corresponding to said individual's metabolic phenotype for said class of N-(aryl substituted)-naphthalidimide as represented by said multi-determinant metabolic phenotype.

45. The method of claim 41, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

46. The method of claim 45, wherein said multi-determinant metabolic phenotype is characterized according to the method comprising:

a) administering to an individual a probe substrate specific to metabolic pathway(s) for said class of N-(aryl substituted)-naphthalidimides compounds;

b) detecting metabolites of said metabolic pathway(s) in a biological sample from said individual in response to said probe substrate; and

c) characterizing respective phenotypic determinants of said multi-determinant metabolic phenotype based on detected metabolites.

47. An assay system for detecting the presence of enzyme-specific metabolites in a biological sample, said

sample obtained from an individual treated with a known amount of at least one probe substrate for a class of N-(aryl substituted)-naphthalidimide compounds, specific for metabolic pathways of said metabolites, said assay comprising:

a) means for receiving said biological sample, including a plurality of affinity complexation agents contained therein;

b) means for detecting presence of said enzyme-specific metabolites bound to said affinity complexation agents; and

c) means for quantifying ratios of said metabolites to provide corresponding phenotypic determinants;

wherein said phenotypic determinants provide a metabolic phenotypic profile of said individual.

48. The assay system of claim 47, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

49. The assay system of claim 48, wherein said step b) or step c) is effected according to the method comprising:

a) administering to an individual a probe substrate specific to metabolic pathway(s) for said class of N-(aryl substituted)-naphthalidimides compounds;

b) detecting metabolites of said metabolic pathway(s) in a biological sample from said

individual in response to said probe substrate; and

c) characterizing respective phenotypic determinants of said multi-determinant metabolic phenotype based on detected metabolites;

wherein said probe substrate is at least one substrate known to be metabolized by said metabolic pathway, and wherein said probe substrate is other than an inducer or inhibitor of said metabolic pathway.

50. The assay system of claim 49, wherein said assay is a ligand binding assay.

51. The assay system of claim 50, wherein said ligand binding assay is selected from the group consisting of immunoassay, enzyme-linked immunosorbent assay (ELISA), microarray formatted immunoassay and microarray formatted ELISA.

52. The assay system of claim 51, wherein said means for receiving said biological sample is a multi-well microplate including said plurality of affinity complexation agents in each well.

53. The assay system of claim 52, wherein said plurality of affinity complexation agents are bound to each well in an array-based format.

54. The assay system of claim 53, wherein said means for detecting said presence of said metabolites bound to said binding agents is a charge-coupled device (CCD) imager.

55. The assay system of claim 47, wherein said means for said quantifying ratios of said metabolites is a densitometer.

56. A method of using an enzyme-specific assay for the individualization of treatment with a class of N-(aryl substituted)-naphthalidimide compounds, which comprises:

a) conducting said assay to identify phenotypic determinants in a biological sample obtained from an individual treated with a probe substrate for said class of N-(aryl substituted)-naphthalidimide compounds;

b) determining a rate of drug metabolism according to said determinants; and

c) determining and/or selecting a safe and therapeutically effective dose of said class of N-(aryl substituted)-naphthalidimide compoundsfor said individual based on said rate.

57. The method of claim 56, wherein said assay comprises:

a) means for receiving said biological sample, including a plurality of affinity complexation agents contained therein;

b) means for detecting presence of said enzyme-specific metabolites bound to said affinity complexation agents; and

c) means for quantifying ratios of said metabolites to provide corresponding phenotypic determinants;

wherein said phenotypic determinants provide a metabolic phenotypic profile of said individual.

58. The method of claim 57, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

59. The method of claim 58, wherein said enzyme-specific assay is selected from the group consisting of immunoassay, enzyme-linked immunosorbent assay (ELISA), microarray formatted immunoassay and microarray formatted ELISA.

60. The method of claim 59, wherein said rate of drug metabolism corresponds to a ratio of phenotypic determinants, wherein said phenotypic determinants are enzyme-specific determinants.

61. The method of claim 60, wherein said ratio is selected from the group consisting of concentration ratio, molar ratio, chiral ratio, ratio of area under the curve and signal peak height ratio.

62. The method of claim 61, wherein said phenotypic determinants comprise phenotypic determinants for N-acetyltransferase-2 (NAT2).

63. The method of claim 62, wherein said phenotypic determinants comprise phenotypic determinants for NAT2 and CYP1A2.

64. The method of claim 63, wherein said phenotypic determinants further comprise phenotypic determinants for any one or more of N-acetyltransferase-1 (NAT1), CYP2A6, CYP2D6, CYP2E1, CYP3A4, CYP2C9, and CYP2C19, UGTs, GSTs, and STs.

65. A method of screening a plurality of individuals for participation in a drug treatment trial assessing the therapeutic effect of a class of N-(aryl substituted)-naphthalidimide compounds , said method comprising:

a) selecting individuals having a metabolic phenotype characterized as effective for metabolizing said class of N-(aryl substituted)-naphthalidimide compounds .

66. The method of claim 65, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

67. The method of claim 66 wherein said multi-determinant metabolic phenotype is determined according to the method comprising:

a) administering to an individual a probe substrate specific to metabolic pathway(s) for said class of N-(aryl substituted)-naphthalidimides compounds;

b) detecting metabolites of said metabolic pathway(s) in a biological sample from said individual in response to said probe substrate; and

c) characterizing respective phenotypic determinants of said multi-determinant metabolic phenotype based on detected metabolites.

68. A method of screening a plurality of individuals for treatment with a class of N-(aryl substituted)-naphthalidimide compounds, said method comprising:

a) genotyping said individuals to identify individuals lacking at least one allelic variation known to prompt toxicity of said class of N-(aryl substituted)-naphthalidimide compounds; and

b) selecting individuals having a metabolic phenoytpe characterized as effective for metabolizing said class of N-(aryl substituted)-naphthalidimide compounds.

69. The method of claim 68, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

70. The method of claim 68 further comprising determining a safe and therapeutically effective amount of said class of N-(aryl substituted)-naphthalidimide compoundsto be administered to each of said individuals lacking said at least one allelic variation, said effective amount corresponding to an individual-specific rate of drug metabolism as determined by phenotypic determinants specific for at least one enzyme known to metabolize said class of N-(aryl substituted)-naphthalidimide compounds.

71. The method of claim 70, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

72. The method of claim 71, wherein said step of characterizing a metabolic phenotype comprises a ligand-binding assay specific for said at least one enzyme known to metabolize said class of N-(aryl substituted)-naphthalidimide compounds.

73. The method of claim 72, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

74. The method of claim 73, wherein said ligand-binding assay is selected from the group consisting of immunoassay, enzyme-linked immunosorbent assay (ELISA),

microarray formatted immunoassay and microarray formatted ELISA.

75. The method of claim 74, wherein said rate of drug metabolism corresponds to a ratio of phenotypic determinants for at least NAT2 enzyme.

76. The method of claim 75, wherein said ratio is selected from the group consisting of concentration ratio, molar ratio, chiral ratio, ratio of area under the curve and signal peak height ratio.

77. The method of claim 76, wherein said ligand-binding assay further provides means to determine phenotypic determinants for at least one of the following enzymes: CYP1A2, NAT1, CYP2A6, CYP2D6, CYP2E1, CYP3A4, CYP2C9 and CYP2C19, UGTs, GSTs, and STs.

78. A method of screening a plurality of individuals for participation in a drug treatment trial assessing the therapeutic effect of a candidate drug treatment, said method comprising:

a) genotyping each of said individuals to identify individuals lacking at least one allelic variation known to prompt the toxicity of said drug; and

b) characterizing a multi-determinant metabolic phenotype of said identified individuals of step a) to determine each individual's ability to metabolize said drug.

79. The method of claim 78, wherein said drug is from a class of N-(aryl substituted)-naphthalidimide compounds.

80. The method of claim 79, wherein said class of N-(aryl substituted)-naphthalidimide compounds includes ammonafide.

81. The method of claim 80, wherein said multi-determinant metabolic phenotype is comprised of at least one determinant indicative of an individual's metabolic capacity for at least one drug metabolizing enzyme.

82. The method of claim 81, wherein said at lest one drug metabolizing enzyme is selected from the group consisting of N-acetyltransferase-1 (NAT1), N-acetyltransferase-2 (NAT2), CYP1A2, CYP2A6, CYP2D6, CYP2E1, CYP3A4, CYP2C9, CYP2C19, UGTs, GSTs, and ST.

83. The method of claim 82, wherein said rate of drug metabolism corresponds to a ratio of said phenotypic determinants for said at least one enzyme.

84. The method of claim 83, wherein said ratio is selected from the group consisting of concentration ratio, molar ratio, chiral ratio, ratio of area under the curve and signal peak height ratio.

85. The method of claim 3, wherein said step b) or step c) is effected using an affinity complexation agent specific to each of said metabolites.

86. The method of claim 1, wherein said step b) and step c) are effected using an affinity complexation agent specific to each of said metabolites.

87. The method of claim 3, wherein said step b) and step c) are effected using an affinity complexation agent specific to each of said metabolites.

88. The assay system of claim 48, wherein said step b) and step c) are effected according to the method comprising:

a) administering to an individual a probe substrate specific to metabolic pathway(s) for said class of N-(aryl substituted)-naphthalidimides compounds;

b) detecting metabolites of said metabolic pathway(s) in a biological sample from said individual in response to said probe substrate; and

c) Characterizing respective phenotypic determinants of said multi-determinant metabolic phenotype based on detected metabolites; wherein said probe substrate is at least one substrate known to be metabolized by said metabolic pathyway, and wherein said probe substrate is other than an inducer or inhibitor of said metabolic pathway.